REMARKS

In response to the November 20, 2002 telephonic interview with Examiner Stucker, applicants herewith submit a set of amended claims that more clearly define applicants' invention. Applicants have taken care not to introduce any new matter. The term "native" as used in the claims is defined at page 44, lines 3-11 of the present application.

The claims currently pending in this divisional application include: composition claims, including claims 40, 82, and new claims 84-86; methods of making the compositions, including claims 42-49; methods of treatments using the compositions, including claims 68 and 71-73; and a screening method that includes claim 74. Examiner Stucker requested that one group be selected for examination. Applicants request that composition claims 40, 82 and new claims 84-86 be examined at this time.

Claims 42-49, 68 and 71-73 are withdrawn at this time with the understanding that when elected compositions claims 40, 82 and new claims 84-86 are found to recite patentable subject matter then all method claims for making and/or using the patentable compositions be rejoined and examined in this one application.

During the November 20, 2002 telephonic discussion Examiner Stucker also requested that applicants choose one of the method of treatments selected from treating HIV, cancer, wasting or promoting a hematopoetic effect because as stated by the Examiner the treatment methods are patentably distinct. In response, applicants have amended method of treatment claims 68 and 71-73 to recite a method to treat HIV. Such amendment is with express reservation of the right to file divisional applications directed to the use of the claimed compounds for methods of treatment for cancer, wasting disease and promoting hematopoeisis, during the pendency of the present application, or during the pendency of a further divisional or continuing application based on and claiming priority of the present invention.

No fee is due for this amendment, however, the U.S. Patent and Trademark Office is hereby authorized to charge any additional amount necessary for the entry of this amendment, and to credit any excess payment, to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

In the event that any issues remain, Examiner Stucker is requested to contact the undersigned attorney at (919) 419-9350 to resolve same.

Respectfully submitted,

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APPENDIX A

Please amend claims 40, 42-46, 48-49, 68, 71 and 82 as follows:

40. A therapeutic [first] composition comprising at least one fraction separated from a [one or more first components of a second composition comprising] a sample of native hCG or native β-hCG, [the first components being separated from other components of the hCG or β-hCG sample, the native hCG or β-hCG sample not being purified to homogeneity in the second composition,] wherein the native hCG or native β-hCG has not being purified to homogeneity; and wherein the at least one fraction has an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD as determined by elution from a gel filtration sizing column relative to the elution of a native hCG heterodimer with a molecular weight of 77 kD, and a β-hCG core protein or peptide with a molecular weight of 10 kD, and is active in inhibiting HIV replication.[the first components and the second composition having] at least one therapeutic effect selected from the group consisting of anti-HIV effects, anti-cancer effects, anti-wasting effects, and pro-hematopoetic effects.]

42. A therapeutic [first] composition produced by a process comprising the following steps:

a) subjecting a sample [second composition] comprising native hCG or native β-hCG to a size fractionation procedure, wherein the native hCG or native β-hCG has not being purified to homogeneity; [in the second composition, the second composition having at least one therapeutic effect selected from the group consisting of anti-HIV effects, anti-cancer effects, anti-wasting effects, and pro-hematopoetic effects;] and

b) recovering fractions that inhibit HIV replication [having such effects].

43. The therapeutic [first] composition of claim 42 wherein the recovered fractions contain material having an approximate [apparent] molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD, wherein the [apparent] molecular weight is determined by elution from a gel filtration sizing column relative to the elution of a native hCG heterodimer, having a molecular weight of 77 kD, and a β-hCG core protein or peptide, having a molecular weight of 10 kD.

44. The therapeutic [first] composition of claim 42, wherein the sample [second composition] is early pregnancy urine.

45. A method for producing a therapeutic [first] composition having [at least one therapeutic effect selected from the group consisting of] anti-HIV effects[, anti-cancer effects, anti-wasting effects, and pro-hematopoetic effects], said method comprising:

a) subjecting a [second composition] sample comprising native hCG or native β-hCG to a size fractionation procedure, wherein the native hCG or native β-hCG has not being purified to homogeneity [in the second composition, the second composition having at least one therapeutic effect selected from the group consisting of anti-HIV effects, anti-cancer effects, anti-wasting effects, and pro-hematopoetic effects]; and

b) recovering fractions active to inhibit HIV infection or replication [or Kaposi's sarcoma or having a pro-hematopoietic effects].

46. The method of claim 45 wherein the size fractionation procedure comprises the steps:

a) loading the sample [second composition] onto a gel filtration sizing column in a first buffer of 30 mM sodium phosphate, pH 8.3;

b) eluting components of the sample [second composition] from the column with second buffer of 30 mM sodium phosphate, pH 7.0 and 2 M sodium chloride; and

c) recovering fractions of the sample [second composition] having been eluted from the column.

48. The method of claim 47 wherein the [second composition] sample is early pregnancy urine.

49. The method of claim 48 wherein prior to subjecting the urine [second composition] to a size fractionation procedure, the sample [second composition] is subjected to the following steps:

a) adjusting the pH of the urine to a pH of approximately 7.2 causing the formation of a precipitate;

b) removing the precipitate from the urine;

c) concentrating the urine;

d) removing salt and lipid from the urine; and

e) lyophilizing the urine.

68. A method of treating [or preventing a condition selected from the group consisting of] an HIV infection [, cancer, wasting, and hematopoetic deficiency,] in a human subject in need of such treatment [or prevention] comprising:

administering to the subject an effective amount of a therapeutic [the first] composition [a therapeutically or preventatively effective amount of a first composition] comprising at least one fraction [one or more first components of a second composition comprising] separated from a sample of native hCG or native β-hCG[the first components being separated from other components of the hCG or β-hCG sample, the native hCG or β-hCG sample] that has not being purified to homogeneity, and wherein the one fraction has an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD determined by elution from a gel filtration sizing column relative to the elution of a native hCG heterodimer with a molecular weight of 77 kD, and a β-hCG core protein or peptide with a molecular weight of 10 kD and is active in inhibiting HIV infection and replication.[in the second composition, the first components and the second composition having at least one therapeutic effect selected from the group consisting of anti-HIV effects, anti-cancer effects, anti-wasting effects, and pro-hematopoetic effects].

71. A method of reducing replication of [treating or preventing a condition selected from the group consisting of] HIV [infection, cancer, wasting, and hematopoetic deficiency,] in a human subject in need of such treatment [or prevention] comprising:

administering to the subject an effective amount of a [first] composition [effective] to treat [or prevent] HIV infection, the [first] composition being produced by a process comprising the following steps:

a) subjecting a sample [second composition] comprising native hCG or native β-hCG to a size fractionation procedure, wherein the native hCG or native β-hCG has not being purified to homogeneity [in the second composition, the second composition having at least one therapeutic effect selected from the group consisting of anti-HIV effects, anti-cancer effects, anti-wasting effects, and pro-hematopoetic effects.]; and

b) recovering fractions that exhibit anti-HIV effects [having such effects].

82. A pharmaceutical composition comprising

a) a [the] therapeutic [first] composition of claim 40; and

b) a pharmaceutically acceptable carrier.

APPENDIX B

All Pending Claims

40. A therapeutic composition comprising at least one fraction separated from a sample of native hCG or native β-hCG, wherein the native hCG or native β-hCG has not being purified to homogeneity; and wherein the at least one fraction has an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD as determined by elution from a gel filtration sizing column relative to the elution of a native hCG heterodimer with a molecular weight of 77 kD, and a β-hCG core protein or peptide with a molecular weight of 10 kD, and is active in inhibiting HIV infection and replication.

42. A therapeutic composition produced by a process comprising the following steps:

a) subjecting a sample comprising native hCG or native β-hCG to a size fractionation procedure, wherein the native hCG or native β-hCG has not being purified to homogeneity; and

b) recovering fractions that inhibit HIV infection and replication.

43. The therapeutic composition of claim 42 wherein the recovered fractions contain material having an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD, wherein the molecular weight is determined by elution from a gel filtration sizing column relative to the elution of a native hCG heterodimer, having a molecular weight of 77 kD, and a β-hCG core protein or peptide, having a molecular weight of 10 kD.

44. The therapeutic composition of claim 42, wherein the sample is early pregnancy urine.

45. A method for producing a therapeutic composition having anti-HIV effects, said method comprising:

a) subjecting a sample comprising native hCG or native β-hCG to a size fractionation procedure, wherein the native hCG or native β-hCG has not being purified to homogeneity; and

b) recovering fractions active to inhibit HIV infection or replication.

46. The method of claim 45 wherein the size fractionation procedure comprises the steps:

a) loading the sample onto a gel filtration sizing column in a first buffer of 30 mM sodium phosphate, pH 8.3;

b) eluting components of the sample from the column with second buffer of 30 mM sodium phosphate, pH 7.0 and 2 M sodium chloride; and

c) recovering fractions of the sample having been eluted from the column.

47. The method of claim 45 wherein the gel filtration sizing column is a SUPERDEX 200™ column and wherein the recovered fractions contain material having an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD, wherein the molecular weight is determined by elution from the SUPERDEX™ 200 column relative to the elution of a native hCG heterodimer, having a molecular weight of 77 kD, and a β-hCG core protein or peptide, having a molecular weight of 10 kD.

48. The method of claim 47 wherein the sample is early pregnancy urine.

49. The method of claim 48 wherein prior to subjecting the urine to a size fractionation procedure, the sample is subjected to the following steps:

a) adjusting the pH of the urine to a pH of approximately 7.2 causing the formation of a precipitate;

b) removing the precipitate from the urine;

c) concentrating the urine;

d) removing salt and lipid from the urine; and

e) lyophilizing the urine.

68. A method of treating an HIV infection in a human subject in need of such treatment comprising: administering to the subject an effective amount of a therapeutic composition comprising at least one fraction separated from a sample of native hCG or native β-hCG that has not being purified to homogeneity, and wherein the one fraction has an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD determined by elution from a gel filtration sizing column relative to the elution of a native hCG heterodimer with a molecular weight of 77 kD, and a β-hCG core protein or peptide with a molecular weight of 10 kD and is active in inhibiting HIV infection and replication.

71. A method of reducing replication of HIV in a human subject in need of such treatment comprising:

administering to the subject an effective amount of a composition to treat HIV infection, the composition being produced by a process comprising the following steps:

a) subjecting a sample comprising native hCG or native β-hCG to a size fractionation procedure, wherein the native hCG or native β-hCG has not being purified to homogeneity; and

b) recovering fractions that exhibit anti-HIV effects.

72. The method of claim 71 wherein the recovered fractions contain material having an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD.

73. The method of claim 72 wherein the molecular weight is determined by elution from a gel filtration sizing column relative to the elution of a native hCG heterodimer, having a molecular weight of 77 kD, and a β-hCG core protein or peptide, having a molecular weight of 10 kD.

82. A pharmaceutical composition comprising

a) a therapeutic composition of claim 40; and

b) a pharmaceutically acceptable carrier.

84. A therapeutic composition comprising at least one fraction separated from a sample of native hCG or native β-hCG, wherein the native hCG or native β-hCG has not being purified to homogeneity, wherein the at least one fraction has an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD when separated using sizing column chromatography, and wherein the at least one fraction is active in inhibiting HIV infection and replication.

85. A pharmaceutical composition comprising

a) a therapeutic composition of claim 84; and

b) a pharmaceutically acceptable carrier.

86. A therapeutic composition comprising at least one fraction separated from a sample of native hCG or native β-hCG, wherein the native hCG or native β-hCG has not being purified to

homogeneity, and wherein the at least one fraction is active in inhibiting HIV infection and replication.